

Appl. No. 09/596,362  
Amendment F & Response dated February 18, 2004  
Reply to Office action of November 18, 2003

### REMARKS/ARGUMENTS

#### **Claims Rejection - 35 USC § 112:**

Independent claims 1 and 13 have been amended to more particularly point out and distinctly claim the subject matter the applicant regards as his invention. The phrase "and/or" has been amended to "and" to clarify that the limitations following the phrase are part of the claimed invention. As amended, claims 1 and 13 comply with the requirements of 35 USC § 112, second paragraph. *See, e.g.,* MPEP § 2173.05(h).

#### **Claims Rejection - 35 USC § 102:**

Claims 1, 2 and 13, as amended, are not anticipated by Umbdenstock (US 5,332,579).

Claims 1 and 2 claim a method for treating alcohol craving through the administration of an alpha-pyrone compound. Umbdenstock teaches a method to enhance diets and assist persons recovering from addiction to health damaging substances comprising the oral administration of a nutritional supplement that contains a great variety of vitamins, minerals, herbs and amino acids. Umbdenstock first describes a nutritional supplement for the treatment of cravings in general. (Col. 8, lines 7-18). Kava kava is not mentioned, or suggested, as an ingredient in the composition for the nutritional supplement taught to treat cravings when craving is discussed by Umbdenstock in the generic.

Umbdenstock next teaches that "[t]he nutritional supplements of the subject invention should be different for each addition." (Col. 9, lines 23-25). Umbdenstock lists those primary and secondary nutrients applicable to all cases to include Vitamins C and A, Beta Carotene, etc., (col. 9, lines 25-30 and table at col. 9, lines 48-69), followed by the preferred formula for treating smoking cessation (col. 9, lines 30-34 and table at col. 10 lines 48-53) and finally for alcohol treatment (col. 9, 34-38 and table at col. 10 line 60 to col. 11 line 7). There is no mention, or suggestion, of the herb kava kava in any of these formulations. Only with respect

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to the treatment of food addiction (col. 9, line 39 to col. 10 line 23) does Umbdenstock even mention kava kava, and then only as one of 14 optional herbs within a composition that emphasizes vitamins, minerals and amino acids.

As appreciated by Umbdenstock, the physiological and psychological underpinnings of cravings are different for different types of substance abuse addictions. *See, e.g., Coffey et al., Trauma and substance cue reactivity in individuals with comorbid posttraumatic stress disorder and cocaine or alcohol dependence*, Science Direct, Vol. 65 Issue 2, 1 January 2002, pages 115-127, a copy of which is enclosed with the mailed copy of this amendment and response.

Moreover, Umbdenstock does not teach any one herb, or even a combination of herbs, for the treatment of substance abuse. Rather, Umbdenstock discloses a method of treating substance-abuse related cravings comprising the oral administration of a nutritional substance that must contain a broad range of vitamins and minerals and, optionally, could contain herbs taken from a broad group that includes kava kava. It is clear from the disclosure in the Umbdenstock patent that Umbdenstock failed to appreciate that kava kava was capable of functioning as an anti-depressive and anti-anxiety agent in the treatment of recovering alcoholics.

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found **if the classes of substituents are sufficiently limited or well delineated**. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. . . . One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

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Compare *In re Meyer*, 599 F.2d 1026, 202 USPQ 175 (CCPA 1979) (A reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite.")

MPEP § 2131.02 (8<sup>th</sup> Ed. 2003). One skilled in the art of nutrition for recovering substance abuse addicts would not, having read Umbdenstock, "at once envisage" the use of kava kava as a central ingredient in a nutritional supplement for the treatment of recovering alcoholics.

Claim 13 claims a non-alcoholic beverage formulated to simulate the taste and aroma of an alcoholic beverage containing at least one alpha-pyrone compound. Umbdenstock teaches a nutritional supplement that may, optionally, contain an alpha-pyrone compound. However, Umbdenstock does not teach a non-alcohol beverage formulated to simulate the taste and aroma of an alcoholic beverage.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." TEMP § 2131 at 2100-69 (8<sup>th</sup> Ed. 2001), *quoting Verdegaal Bros. v. Union Oil Co. Of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir, 1987). Umbdenstock does not teach, expressly or inherently, the use of kava kava as an anti-craving agent for the treatment of alcoholism or a non-alcohol beverage formulated to simulate the taste and aroma of an alcoholic beverage.

#### Claims Rejection - 35 USC § 103:

Claims 1 and 13 are not obvious in view of Umbdenstock (US 5,332,579) in combination with Cody (US 6,045,825).

Claim 1 claims a method for treating alcohol craving through the administration of an alpha-pyrone compound. Umbdenstock teaches a method to enhance diets and assist persons recovering from addiction to health damaging substances comprising the oral administration of a

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nutritional supplement that contains a great variety of vitamins, minerals, herbs and amino acids. In the formula for a supplement to treat food addictions, Umbdenstock mentions kava kava as one of 14 herbs that may optionally be employed together with vitamins, minerals and amino acids. Umbdenstock does not teach a method for the treatment of alcohol addiction through the administration of a composition containing alpha-pyrone.

"Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). . . . See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991)." MPEP § 2143.02. One skilled in the art of treating individuals recovering from substance abuse illnesses would not, in view of Umbdenstock, harbor a reasonable expectation that one of 14 optional herbs could form an effective central ingredient in a nutritional supplement for the treatment of alcoholism.

Umbdenstock teaches away from the claimed invention. According to Umbdenstock, "no individual nutrient generally meets the cellular needs of the addictive individual as effectively as the synergistic aspect of the above-combination of substances." (Col. 8, lines 41-44). Umbdenstock would not consider a supplement that was comprised solely of herbs, or that even emphasized herbs, as being effective in the treatment of cravings. Herbs play a role that is optional, and clearly subservient, to the role played by vitamins, minerals and amino acids in the nutritional formula of Umbdenstock.

Cody teaches a composition containing the herb *Piper methysticum* to diminish the desire for tobacco. Cody does not teach a composition for the treatment of alcoholism. As Umbdenstock mentions kava kava, but appears to specifically omit kava kava when discussing the compositions of supplements to treat smoking addiction, it would be inapposite to combine Umbdenstock with Cody. Moreover, Applicant herein conceived of and began reducing the practice of claimed invention during the period September 14, 1997 and December 12, 1997, prior to the effective date of Cody. See Declaration of Gregory Gene Steiner under 37 C.F.R.

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1.131, attached to the Submission in Request for Continuing Examination dated July 3, 2002. Accordingly, Cody should be disregarded as a reference.

Claim 13 claims a non-alcoholic beverage formulated to simulate the taste and aroma of an alcoholic beverage containing at least one alpha-pyrone compound. Umbdenstock teaches a nutritional supplement that may, optionally, contain an alpha-pyrone compound. Umbdenstock does not teach or suggest a non-alcohol beverage formulated to simulate the taste and aroma of an alcoholic beverage.

"If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious". MPEP § 2143.03 at 2100-126, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Dependent claims 2 through 6 and 10 through 12 include all limitations found in independent claim 1. Dependent claims 14 through 16 include all limitations found in independent claim 13. Dependent claims 2 through 6, 10 through 12, and 14 through 16 are therefore new and unobvious for the same reasons as independent claims 1 and 13.

## CONCLUSION

Applicant has offered amendments to claims 1 and 13 with clarifying language to overcome the Examiner's Section 112 rejection. Applicant is presenting evidence and argument establishing that independent claims 1 and 13 describe subject matter that is both new and unobvious, and should be allowed. As dependent claims 2 through 6 and 10 through 12 include all limitations found in independent claim 1, and dependent claims 14 through 16 include all limitations found in independent claim, the pending dependent claims should likewise be allowed. Accordingly, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

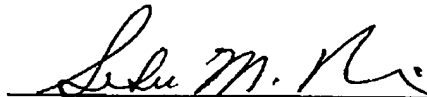
The Examiner is invited to contact the undersigned attorney at (808) 523-8984, business hours Hawaii standard time, or via email at <[sethreiss@lawhi.com](mailto:sethreiss@lawhi.com)>, in order that the

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undersigned attorney may endeavor to resolve any outstanding issues as expeditiously as possible thereby to avoid prolonged prosecution of the present application.

This paper is being mailed and faxed within three months of the November 18, 2003 mailing date of the Office Action to which it responds. The number of independent claims and the total number of claims, after amendment, are within the number paid for with the filing fee.

Respectfully submitted,



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